

833-4

4/29/2014

1/10



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

APR 29 2014

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. John Todhunter
Registration Agent for,
c/o Alex C. Fergusson, Inc.
SRS International Corporation
10234 Three Fox Lane, P. O. Box 109
Delaplane, VA 20144

Subject: Per Ox
EPA Registration Number 833-4
Your Notification Dated April 9, 2014
EPA Received Date April 10, 2014

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA, as amended, to add non-public health pests on the surfaces of raw, unprocessed fruits and vegetables to the product labeling, is acceptable.

This notification has been permanent for this file.

If you have questions concerning this letter, please contact Karen M. Leavy at (703)-308-6237.

Sincerely,

A handwritten signature in black ink that reads "Karen M. Leavy for,".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobials Division(7510P)

2/10

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0080



United States
Environmental Protection Agency
Washington, DC 20460

Registration
 Amendment
 Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 833-4	2. EPA Product Manager Marshall Swindell (PM 33)	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Alex C Fergusson / Per-Ox	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) Alex C Fergusson 5000 Letterkenny Road, Chambersburg, PA 17201 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. 833-4 Product Name Per-Ox	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a notification to add treatment of non-public health organisms (per PR Notice 98-10) on surfaces of raw, unprocessed fruits and vegetables to the product's already approved label (latest approval date, 07-22-2013).

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input checked="" type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	<input type="checkbox"/> Plastic
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
		If "Yes" Package wgt.	No. per container	<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55 Gallons		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product			<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name John A. Todhunter	Title Registration Agent	Telephone No. (Include Area Code) 262-674-8099
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		3. Date Application Received (Stamped)
2. Signature 	3. Title Registration Agent	
4. Typed Name John A Todhunter	5. Date Apr 9, 2014	

3/10



SRS INTERNATIONAL CORP.

10234 Three Fox Lane, PO Box 109 • Delaplane, VA 20144

Tel: (202) 674-8099 / Fax: (540) 364-6083

www.srsinternational.com / todhunter@srsinternational.com

Complete Development Support for Pharmaceuticals, Devices & Specialty Products

April 9, 2014

Marshall Swindell
Product Manager 33
Antimicrobials Division
Office of Pesticides Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: NOTIFICATION for Alex C. Fergusson, Inc.'s Per-Ox
EPA Reg. No. 833-4

Dear Mr. Swindell:

On behalf of our client, Alex C. Fergusson, Inc., we are submitting a NOTIFICATION for a label change for their product "Per-Ox" (EPA Reg. No. 833-4).

This NOTIFICATION is to add non-public health pests on the surfaces of raw, unprocessed fruits and vegetables to the current approved label. The addition of non-public health pests is allowed as a NOTIFICATION per PR Notice 98-10.

The materials in this submission are:

- (a) EPA Form 8570-1 (for a NOTIFICATION with a continuation page certifying compliance with PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and that no other changes have been made to the labeling or the confidential statement of formula of this product.)
- (b) Letter Regarding the Submission (this present letter)
- (c) Proposed Labeling (5 clean copies and also one copy with changes highlighted)

Please let me know any questions in regard to this NOTIFICATION. Per PR Notice 98-10 our client will not distribute product with the above stated amended labeling until 60 days from the date of this NOTIFICATION.

Sincerely,

John A. Todhunter
Registration Agent

4/10

Continuation page to EPA Form 8570-1

EXPLANATION AND CERTIFICATION OF NOTIFICATION

This is a notification to add treatment of non-public health organisms (per PR Notice 98-10) on surfaces of raw, unprocessed fruits and vegetables to the product's already approved label (latest approval date: 07-22-2013).

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.



John A. Todhunter, Ph.D.
Registration Agent for Alex Fergusson Co.

April 9, 2014

PER-OX

For Institutional / Industrial sanitizing of previously cleaned non-porous food contact surfaces in:

- Dairies, Wineries, Breweries and Beverage Plants
- Meat and Poultry Processing/Packaging Plants
- Milk and Dairy Products Processing/Packing Plants
- Seafood and Produce Processing/Packing Plants
- Food Processing/Packing Plants
- Egg Processing/Packing Equipment Surfaces
- Eating Establishments

For Institutional / Industrial sanitizing of previously cleaned, hard, non-porous food contact surfaces such as:

- Eating, Drinking, and Food Preparation Utensils
- Countertops and Food Preparation Surfaces
- Tableware
- Plastic, Glass and Metal Bottles (rinse)

For use as a sanitizer on food contact surfaces in contact with products labeled as organic.

For use as a coarse spray for surfaces to be sanitized or disinfected.

Per-Ox is for sanitizing hard, inanimate, non-food contact surfaces. (general environmental surfaces)

Per-Ox is for use in the disinfection of hard, non-porous surfaces in general commercial environments such as:

- Food processing plants
- Pharmaceutical and chemical facilities

For use as an antimicrobial container rinse to control beverage spoilage microorganisms.

Active Ingredients:	Peroxyacetic Acid	5.25%
	Hydrogen Peroxide	22.00%
Inert Ingredients:	72.75%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN DANGER

See Left Panel for Additional Precautionary Statements

FIRST AID	
If in eyes	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 – 20 minutes • Remove contact lenses, if present, after the first 5 minutes then continue rinsing eyes. • Call a poison control center or doctor for treatment advice.
If on skin or clothing	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 – 20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
If swallowed	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
<p>Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.</p> <p>This product is not to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile area of the body. This product may be used to clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.</p>	

EPA Registration No.: 833-4
EPA Est. No.: 833-PA-1

NET CONTENTS: 53.5 GALLONS
LOT NO.:

CHEMTREC EMERGENCY 800-424-9300
(Chemtrec Customer Number: CCN837)

7/10

Precautionary Statements Hazards to Humans and Domestic Animals

DANGER – Corrosive. Causes irreversible eye damage and skin burns. Harmful if swallowed. May be fatal if absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear (goggles, face shield or safety glasses), chemical resistant apron or coveralls and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove contaminated clothing and wash before reuse.

Physical or Chemical Hazards – Strong oxidizing agent. Mix only with water. Not combustible but at temperatures exceeding 156 °F, decomposition occurs releasing oxygen. The oxygen released could initiate or promote combustion of other materials.

Environmental Hazards – This pesticide is toxic to birds, mammals, fish and aquatic life. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluents containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Storage and Disposal

Do not Contaminate Water, Food, or Feed by Storage and Disposal

Pesticide Storage

NEVER RETURN Per-Ox TO THE ORIGINAL CONTAINER AFTER IT HAS BEEN REMOVED. Avoid all contaminants, especially dirt, caustic, reducing agents, and metals. Contamination and impurities will reduce shelf life and can induce decomposition. In case of a decomposition, isolate container, douse container with cool water and dilute with large volumes of water. Avoid damage to containers. Keep containers closed at all times when not in use. Keep containers out of direct sunlight. To maintain product quality, store at temperatures below 86°F. Do not store on wooden pallets.

Procedure for Leak or Spill

Stop leaks if this can be done without risk. Shut off ignition sources, no flames, smoking, flares, or spark-producing tools. Keep combustible and organic materials away. Flush spilled material with large quantities of water. Undiluted material should not enter confined spaces.

Disposal

Pesticide Disposal

If material has been spilled, an acceptable method of disposal is to dilute with at least 20 volumes of water followed by discharge into suitable treatment system in accordance with all local, state, and Federal environmental laws, rules, regulations, standards, and other requirements. Because acceptable methods of disposal may vary by location, regulatory agencies should be contacted prior to disposal.

Product to be discarded should be disposed of as a hazardous waste after contacting the appropriate local, state, or Federal agency to determine proper procedures.

Container Disposal

Nonrefillable containers less than 5 gallons. Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Empty rinsate into application equipment or mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Empty drums are not returnable unless special arrangements have been made. Dispose of drums in accordance with local, state, and Federal regulations.

Directions For Use

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

For use in circulation cleaning and institutional / industrial sanitizing of previously cleaned hard, non-porous food-contact surfaces and equipment, such as food preparation surfaces, pipelines, tanks, vats, filters, evaporators, pasteurizers and aseptic equipment in:

- Dairies, Wineries, Breweries and Beverage Plants
- Meat and Poultry Processing / Packaging Plants
- Milk and Dairy Products Processing / Packing Plants
- Seafood and Produce Processing / Packing Plants
- Food Processing / Packing Plants
- Egg Processing / Packing Equipment Surfaces
- Eating Establishments
- Final Sanitizing Bottle Rinse

9/10

Per-Ox (833-4): Amendment to Add Raw, Unprocessed Fruits and Vegetables
DRAFT Amended Label RIGHT Panel / TOP HALF - - Proposed Label Changes Highlighted

Sanitizing Hard, Non-Porous Food Contact Surfaces

An effective sanitizer against *Staphylococcus aureus*, *Escherichia coli* and *Salmonella typhimurium*.

Clean equipment immediately after use.

1. Remove gross particulate matter with a warm water flush.
2. Wash equipment with detergent or cleaning solution.
3. Rinse equipment with potable water.
4. Prepare product solution by adding 1.0 to 2.25 fluid ounces to 5 gallons potable water. This provides 90 to 200 ppm peroxyacetic acid and 378 to 852 ppm hydrogen peroxide.
5. Fill closed systems with diluted sanitizer solution and allow a contact time of one (1) minute. If sanitizing at temperatures of 5°C (40°F) or lower, use 2.25 fluid ounces of product to 5 gallons of potable water.
6. If sanitizing against *Listeria monocytogenes*, use 1.25 to 2.25 fluid ounces of this product to 5 gallons potable water. This will provide 112 to 200 ppm of peroxyacetic acid and 454 to 852 ppm of hydrogen peroxide.
7. For open or not completely closed systems, use a coarse spray, mop/wipe or flood technique to apply solution to the surface and allow a contact time of one (1) minute.
8. Allow surfaces to drain thoroughly before resuming operation.

General Environmental (Non-Food Contact) Surfaces Sanitation

Per-Ox is an effective sanitizer on inanimate, hard, non-food contact surfaces against *Staphylococcus aureus* and *Klebsiella pneumoniae*. Sanitization of surfaces such as floors, walls, tables, chairs, benches, drains, etc. can be accomplished using the following procedure:

1. Wash surface/item with a detergent or cleaning solution.
2. Rinse surface/item with potable water.
3. Prepare sanitizer solution by adding 1 to 10 fluid ounces of Per-Ox to 15 gallons of potable water to prepare a solution containing 30 to 300 ppm peroxyacetic acid and 126 to 1262 ppm hydrogen peroxide.
4. Immerse items in diluted sanitizer solution or apply diluted sanitizer solution to surface/item using a mop, wipe, coarse spray, or flood technique. Allow contact for at least 5 minutes.
5. Allow items and/or surfaces to drain adequately or air dry.

For Treatment of Raw, Unprocessed Fruit and Vegetable Surfaces

Can be applied as a dip or spray to control the growth of non-public health microorganisms such as *Xanthomonas campestris* (axonopodis) pathovars citrumelo (citrus canker surrogate) and *Aspergillus versicolor*. Blue mold (*Penicillium* species). Green mold (*Penicillium* species) and stem-end rot (*Geotrichum*) that may cause decay and/or spoilage on raw, post harvest fruits and vegetables during the washing process.

This product can be applied during physical cleaning processes, including at the roller spreader, washer manifold, dip tank, on the brushes or elsewhere in the washing process prior to, simultaneously with, or after detergent wash.

1. Prepare treatment solution by adding 1.0 fluid ounce per 5 gallons of potable water. This will provide 90 ppm peroxyacetic acid and 378 ppm hydrogen peroxide.
2. Apply the diluted sanitizer solution using a coarse spray directed at the fruits or vegetables, or by soaking the fruits and vegetables in the solution. Allow a contact time of at least 45 seconds.
3. The treated produce can be drain dried without a potable water rinse.
4. Do not reuse solution after treatment.

3. Rinse thoroughly with potable water.
4. Prepare product solution by adding 1.0 to 2.25 fluid ounces to 5 gallons potable water. This provides 90 to 200 ppm peroxyacetic acid and 378 to 852 ppm hydrogen peroxide.
5. Immerse all items for at least 2 minutes or for a contact time as specified by the local governing sanitation code.
6. If sanitizing against *Listeria monocytogenes*, use 1.2 to 2.25 fluid ounces of this product to 5 gallons potable water. This will provide 112 to 200 ppm of peroxyacetic acid and 454 to 852 ppm of hydrogen peroxide.
7. Place all sanitized items on a rack or drainboard to drain adequately. Air dry if items will not be reused immediately.

Sanitizing Tableware

For sanitizing tableware in low to ambient temperature warewashing machines, inject the diluted product solution (1.0 to 2.25 fluid ounces of the product to 5 gallons of potable water) into the final rinse water. Allow treated surfaces to air dry.

Final Sanitizing Bottle Rinse

May be used as a final sanitizing rinse for plastic, glass or metal returnable and non-returnable bottles / cans.

1. Wash bottles with detergent or cleaning solution and rinse with potable water.
2. Rinse bottles with a solution prepared by mixing 1.0 to 2.25 fluid ounces of product to 5 gallons of potable water.
3. Allow to drain adequately.

Sanitizing of Hatching Eggs

1. Prepare a dilute solution prepared by mixing 1.0 to 2.25 fluid ounces of product to 5 gallons of potable water.
2. Apply dilute solution as eggs are gathered or prior to setting, as a coarse spray or flood so as to lightly wet all egg shell surfaces.
3. Allow to drain dry.

For Treatment of Raw, Unprocessed Fruit and Vegetable Surfaces (cont)

Can be used on the following raw and post-harvest fruits and vegetables:

- Root and tube vegetables such as carrots and potatoes
- Bulb vegetables such as onions, garlic and shallots
- Leafy vegetables such as broccoli, cabbage and cauliflower
- Legumes such as beans, peas and lentils
- Fruiting vegetables such as peppers, tomato and eggplant
- Cucurbits such as cucumbers, melons, squash and pumpkins
- Citrus fruits such as oranges, lemons, limes and grapefruit
- Pome fruits, apples and pears
- Stone fruits such as cherries, peaches, nectarines and plums
- Small fruits and berries: blackberries, blueberries, red and black raspberries
- Tree nuts such as almond, brazil, filbert, cashew and pecan
- Cereal grains such as corn, barley, oats, rice, and wheat
- Herbs and spices such as basil, chives, coriander and dill
- Miscellaneous fruits and vegetables such as asparagus, avocado, artichoke, banana, cranberry, fig, grapes, kiwifruit, mango, mushrooms, okra, papaya, peanut, pineapple, strawberry and water chestnut.

10/10

Per-Ox (833-4): Amendment to Add Raw, Unprocessed Fruit and Vegetable Surfaces -
DRAFT Amended Label RIGHT Panel / BOTTOM HALF

Hard Surface Disinfection

Per-Ox is an effective broad spectrum disinfectant against Gram positive and Gram negative bacteria including *Staphylococcus aureus* and *Salmonella enterica* and may be used to clean, disinfect, and deodorize hard, non-porous inanimate surfaces such as:

- Food processing equipment and facilities.
- Floors, walls, and other non-porous surfaces such as tables, chairs, counter tops, garbage cans/bins, bathroom fixtures, sinks, shelves, racks, carts, refrigerators, coolers, glazed tile, linoleum, vinyl, glazed porcelain, plastic (such as polypropylene and polyethylene), stainless steel or glass.
- Chemical and pharmaceutical processing facilities and equipment.

To disinfect surfaces that may be contaminated with Gram positive or Gram negative bacteria including *Staphylococcus aureus* and *Salmonella enterica* use the following procedure:

1. Prepare a Per-Ox disinfecting solution by adding 3.2 to 30 oz. of the product of Per-Ox to 5 gallons of potable water. This will provide 288 to 2700 ppm of peroxyacetic acid and 1211 to 11,340 ppm hydrogen peroxide.
2. Remove gross filth from surfaces to be disinfected by cleaning with a suitable detergent or cleaner. Rinse surface with potable water.
3. Apply Per-Ox disinfecting solution by wiping, mopping, or as a coarse spray. Allow at least 10 minutes contact time, then air dry.
4. Applications on food-contact surfaces require a sterile or potable water rinse following disinfection.

Eating Establishment Sanitizing

An effective sanitizer against *Staphylococcus aureus*, *Escherichia coli* and *Salmonella typhimurium*.

1. Scrape/prewash plates, utensils, cups, glasses, etc. whenever possible.
2. Wash all items with a detergent.

(Note: this section continues at top of next column (i.e.: Right Panel TOP Half)

Sanitizing of Conveyors, Peelers, Slicers and Saws for Meat, Poultry, Seafood, Fruits and Vegetables

An effective sanitizer against *Staphylococcus aureus*, *Escherichia coli* and *Salmonella typhimurium*.

For use in the static or continuous washing, rinsing, and sanitizing of conveyor equipment, peelers, collators, slicers, saws, etc.

1. Remove all products from equipment if during treatment the sanitizer will directly contact the items.
2. Prepare sanitizer solution by adding 1.0 to 2.25 fluid ounces to 5 gallons of potable water.
3. Apply sanitizer solution to the return portion of the conveyor or to the equipment by using a coarse spray or other means of wetting the surfaces. Treat for at least 1 minute. Control the volume of solution so as to permit maximum drainage and to prevent puddles. The conveyor may still be damp when food contact occurs.
4. If sanitizing against *Listeria monocytogenes*, use 1.2 to 2.25 fluid ounces of this product to 5 gallons potable water. This will provide 112 to 200 ppm of peroxyacetic acid and 454 to 852 ppm hydrogen peroxide.
5. Allow equipment to drain adequately before reusing, a dry surface is not required.

Antimicrobial Rinse of Pre-Cleaned or New Returnable or Non-Returnable Containers:

To reduce the number of nonpathogenic beverage spoilage organisms such as *Aspergillus versicolor*, *Byssochlamys fulve*, *Pediococcus damnosus*, *Lactobacillus buchneri* and *Saccharomyces cerevisiae*.

1. Prepare solution by adding 7.0 to 30 fluid oz. to 5 gallons of potable water. This will provide 632 to 2707 ppm of peroxyacetic acid and 2650 to 11,354 ppm hydrogen peroxide.
2. Apply solution, allowing a minimum contact time of 5 seconds.
3. Allow containers to drain thoroughly, and then rinse with sterile or potable water.



Alex C. Ferguson
5000 LETTERKENNY RD.
CHEMBERSBURG, PA 17201
Tel: 1-800-345-1329